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10/572,664	03/20/2006	Jonathan Robert Rhoades	8502-US	4631

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Nestle HealthCare Nutrition
12 Vreeland Road
2nd Floor
Florham Park, NJ 07932

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent.dept@gerber.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,664	RHOADES ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *March 20, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/EP04/10469, filed September 17, 2004, which claims priority to foreign application GB03212996.1, filed September 19, 2003. Claims 12-29 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted March 20, 2006 is acknowledged wherein claims 1-11 are cancelled and new claims 12-29 are introduced.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

As entered, the claims contain two claims numbered 26. Misnumbered claims 26-29 have been renumbered 27-30. In all documents relating to this application the second claim 26 will be referred to as claim 27 and original claims 27-30 will be referred to as claims 28-30.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 12-26 and 28-30, drawn to compositions of various oligosaccharides and methods of using the same.

Group II, claim(s) 27, (previously numbered claim 26) drawn to a method of screening oligosaccharides for anti-adhesive activity.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature shared between the two groups is merely the concept of oligosaccharides having anti-adhesive activity. Such oligosaccharides are known in the prior art, for example the oligosaccharides disclosed by Guggenbichler et al. (US patent 5683991, cited in PTO-1449) as described below. Therefore any special technical feature over the prior art must be derived from the specific oligosaccharides used, a feature which will not be present in a screening method which by definition is performed on novel oligosaccharides of undefined activity. Therefore the claims lack a shared special technical feature.

During a telephone conversation with Gary Lobel on July 22, 2008 a provisional election was made without traverse to prosecute the invention of group 1, claims 12-26 and 28-30. Affirmation of this election must be made by applicant in replying to this Office action. Claim 27 (previous claim 26) is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18, 21, and 27-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 21, and 27-29 provide for the use of oligosaccharide compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 24 recites the broad recitation manno-oligosaccharides and/or methyl manno-oligosaccharides, and the claim also recites the limitation "in particular chosen from alpha 1,2-mannobioses, alpha 1,3-mannobioses, alpha 1,6-mannobioses, or methyl alpha manno-oligosaccharides," which is the narrower statement of the range/limitation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-23 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating, reducing, or

inhibiting the invasion and infection of mammalian cells by pathogen, does not reasonably provide enablement for methods of preventing the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a therapeutic method for treatment or prevention of a microbial infection. In the absence of an explicit definition in Applicant's specification, the claims are given their broadest reasonable interpretation. See MPEP 2111. Merriam-Webster's Collegiate Dictionary (reference included with PTO-892) defines "prevent" as meaning, "to deprive of power or hope of acting or succeeding," or "to keep from happening or existing." This definition is taken as representing the ordinary usage of the term "preventative". In order to deprive something of power or hope of acting or succeeding, the preventative agent must be completely effective. "Prevention" as recited in the instant claims, is interpreted to mean

the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Merely slowing the onset of disease or making the disease less likely would still leave it with "power or hope of acting or succeeding," and thus not qualify as prevention.

The state of the prior art: Various oligosaccharides are known to exert a probiotic activity on the intestinal microflora. This effect can inhibit the colonization of the intestines by pathogenic microorganism and improve intestinal health. However, this treatment does not qualify as a preventative treatment in the sense described above under the heading "Nature of the invention"

More generally, prevention of any disorder in the sense being used herein is not a recognized clinical outcome in the art, as no treatment is perfectly effective.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms? For example, will a metastatic cancer eventually adapt to overcome treatments directed to preventing it from metastasizing into the bone? Or will a case of osteoporosis or rheumatoid arthritis ultimately progress to a point where symptoms develop regardless of which therapy is administered.

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer.

The Breadth of the claims: In the absence of an explicit definition in Applicant's specification, "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Any therapy which merely reduces the number or severity of symptoms, or which is effective for a period shorter than the subject's remaining lifespan, is considered to be ineffective at preventing a disorder.

The amount of direction or guidance presented: The claimed oligosaccharides are disclosed to inhibit adhesion of pathogenic bacteria, which would be expected to be a beneficial effect to subjects suffering from or exposed to pathogenic intestinal microorganisms. However, no guidance is given in the specification suggesting any reason to believe that administration of these oligosaccharides can fully prevent any adhesion of pathogenic microorganisms at any future point in time.

The presence or absence of working examples: All of the examples provided concern the *in vitro* adhesion of bacteria to cells in culture. No working examples are provided demonstrating long-term preventative activity in a living subject.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. In particular, one skilled in the art, in order to practice the invention for prevention of disease, would need to know whether the preventative effect remains potent over the long term.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal

tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or monkeys, or a human clinical trial. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering the claimed compounds for a period of years to a suitable subject population is an undue amount of experimentation needed in order to practice the full range of the claimed invention. As prevention in the full sense is an extremely high bar for any clinical outcome, there is no reason to believe that the therapy would be successful, and any actual success would be a surprising and unpredictable result.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the nature of the invention and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of adhesion of pathogenic bacteria.

Claims 12-26 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions and methods for treating enteric bacterial disorders and infections, does not reasonably provide enablement for treating all pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed method is a method of treating various infectious diseases. In order to be enabled to make and use the invention, one skilled in the art must be able to determine which disorders can be treated by the claimed method and must then have sufficient guidance to successfully treat the full range of said disorders.

The state of the prior art: Prebiotic oligosaccharides, which are non-digestible oligosaccharides that can be fermented by beneficial enteric bacteria species such as *Bifidobacterium* or *Lactobaccilli*, are known in the prior art to improve enteral health by

promoting the growth of beneficial bacteria and inhibiting the growth and/or attachment of pathogenic bacteria. This effect is only known to be effective against pathogenic bacteria, as opposed to other pathogens such as viruses and protozoa. For example, MacFarlane et al., (Reference included with PTO-1449) in reviewing what is known about probiotic and prebiotic therapies, discusses inhibition of **bacterial** infections and makes no mention of inhibition or treatment of pathogenic viruses or protozoa. Furthermore, prior are broad-spectrum agents capable of killing all classes of pathogenic microorganisms are generally very non-specific in their destructive action (e.g. heat sterilization, bleach, alcohol, detergents) and cannot be used to kill pathogens internally without seriously injuring or killing the host organism. Thus the prior art only contemplates using the claimed oligosaccharides against pathogenic bacteria.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Common microbial pathogens comprise bacteria, viruses, and protozoa. These three families of pathogens are distinct and unrelated, although they can often produce similar symptoms (e.g. diarrhea, gastroenteritis) when infecting a particular tissue. The degree of unrelatedness is such that there is no expectation whatsoever that a therapy that targets one class of pathogen will have any activity against another. While bacteria colonize the gut by a particular process which is inhibited by the claimed oligosaccharides, other pathogens infect and damage the host organism by different methods and cannot be expected to thereby be susceptible to a therapy directed against a particular stage of bacterial

pathogenesis. Therefore the activity of the claimed oligosaccharides against non-bacterial pathogens is highly unpredictable.

The Breadth of the claims: The claimed invention is very broad, encompassing any oligosaccharide composition or method for treating any enteric disorder caused by a pathogen, regardless of which pathogen is responsible.

The amount of direction or guidance presented: The instant specification discusses antibacterial effects of the claimed composition, specifically in its ability to inhibit adhesion of pathogenic bacteria. The specification does not discuss any antiviral, antiprotozoal, antiparasitic, immunostimulating, or other activity of the disclosed oligosaccharides that could be expected to treat or inhibit infection by non-bacterial pathogens, and does not mention any specific nonbacterial pathogens.

The presence or absence of working examples: The specification provides examples of the claimed oligosaccharides inhibiting adhesion of pathogenic bacteria to cultured cells *in vitro*. No examples are provided of any activity against any non-bacterial pathogen.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as broad-spectrum treatment of disease. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the full scope of the claimed invention one skilled in the art would have to develop methods for treating all types of pathogens beyond merely treating bacterial pathogens. This task would have to be carried out without any guidance from the prior art or from Applicant's

disclosure. Essentially, one skilled in the art would be starting from scratch with nothing to go on besides Applicant's assertion that the invention includes compositions and methods for treating pathogen-associated enteric disorders. Research would need to be done to assess the viability of these therapeutic agents against a wide variety of different pathogenic agents in suitable animal models, and to develop protocols for treating so many unrelated diseases. This undertaking would require an undue burden of unpredictable experimentation to practice the invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention for treating all possible pathogenic organisms.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14, 16-22, 25, 26, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Guggenbichler et al. (US patent 5683991, cited in PTO-1449)

Guggenbichler et al. discloses oligogalacturonides having a degree of polymerization of 2-7. (column 1 line 62 - column 3 line 44) These oligosaccharides can also be considered to be non-esterified pectic oligosaccharides because they are short fragments of a pectin chain. They are useful for blocking attachment of bacteria and for treating infections of the gastrointestinal tract, for example colonization of the small intestine. (column 2 lines 45-59) Therefore the compositions comprise the same ingredients as the instant claims and the methods comprise administering the same ingredients to the same subjects. For these reasons Guggenbichler et al. anticipates the claimed invention.

Claims 12, 13, 16-21, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Baillon et al. (PCT international publication WO01/65949, cited in PTO-1449)

Baillon et al. discloses a method of treating pathogenic bacteria in an animal by administering a non-digestible carbohydrate. (p. 3 lines 21-23) Non-digestible carbohydrates include galactooligosaccharide and lactosucrose. (p. 4 lines 1-6) Pathogenic bacteria that can be treated in this manner include *Campylobacter jejuni*, *Clostridium*, *Salmonella*, and pathogenic *Escherichia coli*. (p. 6 lines 23-27) These pathogens cause various symptoms including diarrhea. (p. 1 line 12 - p. 2 line 24) Therefore the compositions comprise the same ingredients as the instant claims and the

methods comprise administering the same ingredients to the same subjects. For these reasons Baillon et al. anticipates the claimed invention.

Claims 12-14 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama et al. (PCT international publication WO98/42311, cited in PTO-1449)

Akiyama et al. discloses a pharmaceutical composition comprising an active ingredient and a curdlan. (p. 3 lines 13-32) In one embodiment the composition is an anti-*Heliobacter pylori* composition. (p. 4 lines 5-6) These compositions containing curdlan anticipate the instant claims.

Claims 12-14 and 16-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin-Sosa et al. (Reference included with PTO-892)

Martin-Sosa et al. discloses sialylated milk oligosaccharide fractions. (p. 3068, left column paragraph 5, right column paragraph 2) These compositions are considered to be nutritional or pharmaceutical compositions containing oligosaccharides according to the invention. The sialylated oligosaccharides in human and bovine milk are shown to inhibit hemagglutination of erythrocytes by pathogenic *Eschericha coli*. (p. 3069, left column paragraph 1 – p. 3070 left column paragraph 2) These bacteria adhere to host epithelial cells and are a major cause of diarrhea in children.

Therefore Martin-Sosa et al. anticipates the claimed invention.

Claims 12-17 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al. (Reference included with PTO-892)

Yokoyama et al. discloses the synthesis of alpha 1-6 mannooligosaccharides in a membrane fraction of *M. segmentis*. (p. 21622 paragraph 4 – p. 21623 paragraph 2) This oligosaccharide product is reasonably considered to be a pharmaceutical or nutritional composition according to the instant claims as it could be administered to a subject to produce a therapeutic effect. Therefore Yokohama et al. anticipates the claimed invention. Note that claim 24 is given its broadest reasonable interpretation, namely as including all manno-oligosaccharides and methyl manno-oligosaccharides.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-22, 25, 26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin-Sosa et al. (Reference included with PTO-892)

The disclosure of Martin-Sosa et al. is discussed above. Martin-Sosa et al. does not disclose a method of treating a disorder by administering the disclosed sialylated oligosaccharides.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the sialylated milk oligosaccharides to a patient suffering from

diarrhea caused by pathogenic *E. coli*. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Martin-Sosa et al. already discloses that these compounds block hemmaglutination and adhesion of these pathogens. One of ordinary skill in the art would reasonably have expected success because administering a known therapeutic agent to a patient is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
7/23/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623